ARC 3743C

PHARMACY BOARD[657]

Adopted and Filed

Rule making related to cannabidiol products

The Board of Pharmacy hereby amends Chapter 10, "Controlled Substances," and Chapter 37, "Iowa Prescription Monitoring Program," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code sections 124.301, 124.552 and 147.76.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code section 124.552 and 2017 Iowa Acts, chapters 152 and 162.

Purpose and Summary

2017 Iowa Acts, chapter 162, requires the Board to adopt rules to administer new Iowa Code section 124.201A, which relates to cannabidiol investigational products and which requires the Board to reschedule a cannabidiol product upon being approved by FDA and rescheduled by DEA. 2017 Iowa Acts, chapter 152, allows the Board to provide information from the drug prescribing and dispensing information program (Iowa Prescription Monitoring Program) to a medical examiner investigator recognized by the State Medical Examiner's office when the information relates to an investigation being conducted by the medical examiner or investigator. This rule making implements those legislative provisions. The rule making also increases the frequency of a dispenser's reporting of controlled substance dispensing to the Iowa Prescription Monitoring Program (PMP) from "at least weekly" to "no later than the next business day following dispensing" to provide prescribers and pharmacists more timely information when utilizing this data in their prescribing and dispensing decision making.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on December 20, 2017, as **ARC 3505C**. Comments supporting the adoption of these amendments were received from one pharmacist and from the Iowa Pharmacy Association. No opposing comments were received. No changes from the Notice have been made.

Adoption of Rule Making

This rule making was adopted by the Board of Pharmacy on March 14, 2018.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Board for a waiver of the discretionary provisions, if any, pursuant to 657—Chapter 34.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on May 16, 2018.

The following rule-making actions are adopted:

ITEM 1. Adopt the following **new** subrule 10.38(3):

10.38(3) *Cannabidiol investigational product.* If a cannabidiol investigational product approved as a prescription drug medication by the United States Food and Drug Administration is eliminated from or revised in the federal schedule of controlled substances by the DEA and notice of the elimination or revision is given to the board, the board shall similarly eliminate or revise the prescription drug medication in the schedule of controlled substances. Such action by the board shall be immediately effective upon the date of publication of the final regulation containing the elimination or revision in the Federal Register.

ITEM 2. Amend subrule 37.3(3) as follows:

37.3(3) *Reporting periods.* A record of each reportable prescription dispensed shall be submitted by each dispenser ~~at least weekly~~ no later than the next business day following dispensing. Records may be submitted with greater frequency than required by this subrule. ~~Records of reportable prescriptions dispensed between Sunday and Saturday each week shall be submitted no later than the following Wednesday. However, a pharmacy that is currently submitting prescription dispensing records to another state's PMP on an alternative weekly reporting schedule may request authority to submit records to the Iowa PMP pursuant to that established schedule. The request shall be submitted in writing via e-mail, fax, or regular mail to the PMP administrator. The request shall identify the pharmacy by name, address, and Iowa pharmacy license number and shall define the alternative reporting period and the reason for the requested alternative reporting period. The PMP administrator is hereby authorized to approve or deny the pharmacy's alternative weekly reporting schedule.~~

ITEM 3. Adopt the following **new** subrule 37.4(9):

37.4(9) *Medical examiner or medical examiner investigator.* A medical examiner or medical examiner investigator may obtain PMP information when the information requested by the examiner or investigator relates to an investigation being conducted by the examiner or investigator.

[Filed 3/20/18, effective 5/16/18]
[Published 4/11/18]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 4/11/18.